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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,128	12/24/2003	John C. Reed	66821-0058	1734
41552 7590 03/19/2008 MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122				
EXAMINER AUDET, MAURY A				
ART UNIT		PAPER NUMBER		
1654				
MAIL DATE		DELIVERY MODE		
03/19/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/748,128

**Applicant(s)**

REED ET AL.

**Examiner**

MAURY AUDET

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 69, 72-75 and 78-129 is/are pending in the application.
- 4a) Of the above claim(s) 83-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69, 72-75, 78-82 and 88-129 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/26/07 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's amendment and response of 10/1/07 is acknowledged. New claims 87-129 are filed herein. Claims 83-87 remain withdrawn as to the non-elected method (appropriate claim identifier is required in response hereto as to claim 83). Claims 69, 72-75, 78-82, and 88-129 are examined on the merits as drawn to the elected TPI 927 compounds and complexes thereof (products). Due to the new grounds of rejection under 35 USC 103, the present action is sent being sent NON-FINAL.

### ***Claim Rejections - 35 USC § 102***

Applicant's arguments over his previous work, Nefzi et al. is deemed persuasive as to the 102 rejection. But is not found persuasive as to the new grounds under 103. Applicant's arguments over Stebani et al. are deemed persuasive in their entirety.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 69, 72-75, 78-82, and 88-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nefzi et al. (Tetrahedron Letters (2000), 41(29), 5441-5446). Is it noted that Nefzi et al. is Applicant's own previous work.

As discussed in the previous action, Nefzi et al. teach an efficient two-step synthesis of mono-, di-, and triureas from resin-bound amides, which bear very close (if not express) limitations with the core structure options to that of elected TPI 927. See e.g. RN 295343-42-9 in the attached reference.

In the previous action, Applicant argues firstly, that Nefzi et al. does not teach the same stereochemistry as Applicant. This is not deemed persuasive, as neither does Applicant. Secondly, Applicant argues that Nefzi et al. does disclose a phenylpropyl substituent off the R3 position, as opposed e.g. other various close variants thereof, such as phenylethyl, as Applicant claims at R3 (differing only by a single C (carbon) extension)).

Based on a reanalysis of Nefzi et al., Applicant's own earlier work directed to the same products/intended use, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to create the TPI-927 compound with e.g. phenylethyl at position R3, or other well known/structurally related variants/analogs/homologs (namely as functional equivalents off the 3 R groups stemming from the required core structure) which Applicant was in possession of and processing greater than one year before the earliest effective filing date of the present application, absent evidence to the contrary that such minor substituent

variations would not have led one of ordinary skill in the art to reasonably expect the same or closely similar results therefrom (e.g. in derepressing an inhibitor of IAP-inhibited caspase).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/M. A./3/1/2008

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/Maury Audet/

Primary Examiner, Art Unit 1654